FILED
OCT 22 1997
CLERK

No. 97-0513

In The

Supreme Court of the United States

October Term, 1996

ARTHUR FRY,

Petitioner,

vs.

ALLERGAN MEDICAL OPTICS, INC.,

Respondent.

On Petition for Writ of Certiorari to the Rhode Island Supreme Court

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether state and common law claims are "requirements", as that term is used in 21 U.S.C. § 360k(a) of the Medical Device Amendments to the Food, Drug and Cosmetic Act, so as to preempt and bar such claims asserted against a premarket approved medical device?

LIST OF PARTIES

Arthur Fry, Petitioner

Allergan Medical Optics, Inc., Respondent

RULE 29.6 STATEMENT

Allergan Medical Optics, Inc. is a wholly-owned subsidiary of Allergan, Inc.

I

STATEMENT OF THE CASE

Petitioner, Arthur Fry has had serious and chronic problems with both eyes for over 13 years, including a detached retina, glaucoma and cataracts.

On March 13, 1990 petitioner underwent cataract surgery and an iridectomy (a surgical removal of part or all of the iris) on his left eye. As part of that procedure he had an AC-21B Anterior Chamber Intraocular Lens (the "lens") implanted in that eye. The lens dislocated twice and had to be repositioned. Ultimately, it had to be removed.

Allergan Medical Optics, Inc. ("Allergan") has been the exclusive manufacturer and distributor of the lens since 1986. The FDA has regulated and continues to regulate the lens, first under an investigational device exception ("IDE") and later under its premarket approval process. Initially Allergan investigated the lens for four years as an IDE device under the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* ("MDA"). It later applied to the FDA for premarket approval under the MDA to market the lens commercially. Allergan submitted with its application extensive information about the safety and effectiveness of the lens. *See* 21 U.S.C. § 360e; 21 C.F.R. Part 814.

The FDA considered the application for more than two years before it granted premarket approval on September 29, 1989. Petitioner's physician implanted the lens six months later on March 13, 1990.

Petitioner sued Allergan on April 13, 1993, in negligence, strict liability and breach of express and implied warranty, claiming that the lens was defective and damaged his left eye. Allergan propounded interrogatories to pinpoint the defect(s) petitioner

claimed and moved three times to compel specific responses. As the Rhode Island Supreme Court observed, "the [petitioner's] responses to interrogatories were elusive at best . . ." *Fry v. Allergan Medical Optics, Inc.*, 695 A.2d 511, 517 n.4 (R.I. 1997). Allergan moved for summary judgment on all counts on the grounds that the MDA preempted each of petitioner's state and common law claims. On February 13, 1995 the Rhode Island Superior Court granted Allergan's motion.

The Rhode Island Supreme Court affirmed the judgment on June 17, 1997 with the opinion appended to the petition.

REASONS FOR DENYING THE WRIT

I. THE RHODE ISLAND SUPREME COURT CORRECTLY APPLIED FEDERAL LAW TO THE FACTS OF THIS CASE.

The Rhode Island Supreme Court held that the MDA preempted and barred petitioner's state and common law claims attacking a premarket approved medical device. The central tenet of the court's holding was that the FDA's premarket approval process created federal requirements which preempt the state requirements flowing from petitioner's state and common law claims. Petitioner contends that state or common law claims can never impose state "requirements" as that term is used in 21 U.S.C. § 360k(a), and that the Rhode Island Supreme Court's opinion conflicts with this Court's interpretation of state "requirements" in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). Petitioner is wrong.

The Rhode Island Supreme Court's opinion is entirely consistent with, and follows this Court's guiding principles set out in, the *Cipollone* and *Lohr* opinions. Just as this Court in *Cipollone* held that requirements "easily" encompass tort actions because

"[state] regulation can be as effectively exerted through an award of damages as though some form of preventive relief", 505 U.S. at 521, the Rhode Island Supreme Court found that the petitioner's tort claims would lead to the same state requirements the MDA expressly preempt.[1] Five of this Court's justices in *Lohr* recently arrived at the same conclusion. 116 S. Ct. 2259-60, 2262. Justice Breyer illustrated the point precisely:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law outlined in the "2-inch" MDA regulation, preempts the state "1-inch" agency regulation, why would it not similarly preempt a state tort law action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)?

Id. at 2259.

Petitioner does *not* question the Rhode Island Supreme Court's holding that the FDA's premarket approval of a device creates preempting federal requirements. Nor could he. Here again, the Rhode Island Supreme Court's decision is consistent with this Court's *Lohr* decision.

Although *Lohr* did not involve premarket approved devices directly, all three *Lohr* opinions address such devices. The Breyer and O'Connor opinions point inescapably to the conclusion that

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1. Petitioner did not allege in any of his claims that Allergan failed to comply with federal standards.

the MDA preempt common law claims asserted against premarket approved devices. The O'Connor plurality in *Lohr* found that even the less rigorous § 501(k) clearance procedure creates federal requirements that preempt common law claims. *Id.* at 2264. Justice Breyer joined the Stevens' plurality's remarks about the rigor of the FDA's premarket approval procedure, keying on device safety and efficacy, and contrasting premarket approval from the abbreviated § 510(k) clearance procedure. Significantly, he would not join in Justice Stevens' prediction that the future instances of preemption under the MDA would be "few" or "rare". *Id.* at 2261-62.

The Breyer and O'Connor opinions leave no doubt that premarket approval creates preempting federal requirements under the MDA. Lower courts have agreed. *See, e.g., Mitchell v. Collagen Corp.*, No. 94-3946, 1997 WL 584550 (7th Cir. Sept. 23, 1997); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110 (1996), *cert. denied*, 117 S. Ct. 143 (1997).

II. THE MAJORITY OF LOWER COURTS HAVE HELD CORRECTLY THAT "REQUIREMENTS" ENCOMPASS COMMON LAW CLAIMS.

Petitioner contends that a conflict between courts over whether the term requirement applies to common law claims warrants certiorari. But the four cases petitioner cites reveal little conflict.

The *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997), and *Martin v. American Medical Systems, Inc.*, 116 F.3d 102 (4th Cir. 1997), cases petitioner cites do not hold that state and common law claims are not requirements under the MDA, but rather, those courts simply held, consistent with *Lohr*, that the FDA's § 510(k) premarket notification process generally does not create preempting federal requirements. The *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir.), *cert. denied*, 66 U.S.L.W. 3107 (October 6, 1997), case

squarely supports the majority position that state requirements include common law claims. *Id.* at 741. Only the *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) case holds that a negligent failure to warn claim is not a state requirement subject to preemption by the FDA's requirements incident to premarket approval. *Id.* at 789.

Because this Court, in *Cipollone* and *Lohr*, has already spoken directly and clearly on this issue, the majority of courts have correctly interpreted the MDA's requirement provision to encompass state and common-law claims. *See, e.g., Mitchell v. Collagen Corp.*, No. 94-3946, slip op. at 22 (7th Cir. Sept. 23, 1997); *Papike v. Tambrands, Inc.*, 107 F.3d at 741; *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1094 (6th Cir. 1997), *petition for cert. filed*, 65 U.S.L.W. 3755 (May 1, 1997); *Duvall v. Bristol-Myers Squibb Co.*, 103 F.3d 324, 329 (4th Cir. 1996).

CONCLUSION

The Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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